

# Morgan Lewis

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December 11, 2024

**VIA CM/ECF**

Honorable Jennifer L. Hall  
J. Caleb Boggs Federal Building  
844 N. King Street  
Wilmington, DE 19801-3555

Re: Nippon Shinyaku Co. v. Sarepta Therapeutics, Inc., C.A. No. 21-1015-JLH

Dear Judge Hall:

Pursuant to the Court's instruction at the December 9, 2024 pretrial conference in the above-referenced action, Nippon Shinyaku Co., Ltd. and NS Pharma, Inc. (collectively, "NS") and Sarepta Therapeutics, Inc. and the University of Western Australia (collectively, "Sarepta") write to provide the Court with their positions on the issues set forth below.



## **I. Interpreter for Trial**

**NS's Position:** Sarepta is using the need for an interpreter as a vehicle to disrupt NS's case preparation and trial presentation. Sarepta's continued objection to NS's preferred interpreter, Ms. Yumi Schweizer, and insistence that at most a neutral interpreter can work with NS's attorneys (but not its witnesses) for no more than two hours is absurd. As the Court noted, it puts NS at a disadvantage because Sarepta can fully practice its direct examinations with its witnesses while NS cannot. There is no debate that Ms. Schweizer is qualified, and given her familiarity with the terminology at issue in this matter, she is the most likely candidate to provide the clearest and least disruptive translations for all parties.

The transcripts and videoclips the parties submitted to the Court only emphasize the disruption in testimony that will occur if NS is forced to use a "cold" interpreter—even one that has been educated on basic terms in the case. It will cause delay, waste the jury's time, and has the potential to create the false impression that the witnesses themselves lack knowledge or are unprepared. These risks are only amplified by Sarepta's proposed interpreter—Ms. Marie Pappas—who appears to be unqualified. Indeed, the only patent/pharmaceutical experience that Sarepta identifies is her written translation of patents, which says nothing about her ability to translate oral testimony in a live, court setting. Further, should the Court order a neutral interpreter, NS would still need to have a check

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interpreter, particularly if it orders the parties to proceed with Ms. Pappas, to ensure that the testimony going into the trial record is accurate.

Sarepta's accusation that Ms. Schweizer was in any way obstructionist is inaccurate. As the videoclips demonstrate, Ms. Schweizer intervened when the lead interpreter offered incomplete or inaccurate translation or when the interpreter needed assistance. NS hopes to avoid such intervention at trial. To the extent that Sarepta continues in its unfounded objection to Ms. Schweizer, NS will offer Ms. Yaejoong Watkins as an alternative interpreter or check interpreter. Ms. Watkins defended Dr. Takeda's deposition in this case and is also a well-qualified and highly respected interpreter in the field.

To alleviate any prejudice in presentation, NS reiterates its offer to "freeze" Ms. Schweizer or Ms. Watkins over the weekend and make either solely available to Sarepta to ensure the smooth translation of their cross-examination questions.<sup>1</sup>

Sarepta alleges that NS has not been diligent in seeking an "agreeable" neutral interpreter that could represent both parties equally. Sarepta is presenting a false choice. Sarepta's absolute refusal to allow any interpreter to work with NS's witness "*ex parte*" in preparation for their direct testimony unfairly prejudices NS, regardless of its choice of interpreters. Thus, until the Court resolves this issues, NS is unable to propose an acceptable interpreter.

In the event that the Court entertains Sarepta's argument, NS would agree to jointly engage Mr. Paul Hersey, with whom NS has no prior existing relationship. Mr. Hersey is highly qualified.<sup>2</sup> **NS, however, needs the right to work with Mr. Hersey beginning today *ex parte* so it can prepare its witnesses for their trial testimony.**<sup>3</sup> As discussed above, precluding NS from adequately preparing for trial would be highly damaging to its case. Additionally, should the Court be persuaded by Sarepta's claims of bias, NS proposes that Sarepta use its own interpreter on cross-examination, subject to NS's check interpreter. This would at least allow NS to prepare for and efficiently present its direct examination at trial.

**Sarepta's Position:** Sarepta proposes a single, mutually agreeable interpreter for the reasons set forth in paragraph 54 and footnote 2 of the Proposed Amended Pre-Trial Order (D.I. 646), and as discussed in the Pretrial Conference. Sarepta has proposed Ms. Marie Pappas as a neutral interpreter. She is highly qualified (as a registered court interpreter, she has interpreted for more than 30 cases and depositions and has translated hundreds of

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<sup>1</sup> NS would also agree that Sarepta could formally and separately engage Ms. Schweizer or Ms. Watkins to interpret on Sarepta's behalf during trial and pay the interpreter directly for her services, including the time she works with them on cross-examination.

<sup>2</sup> See <https://paulhersey.weebly.com/cv.html>.

<sup>3</sup> NS does not agree that Ms. Pappas is sufficiently qualified to act as an interpreter in this manner and reserves the right to propose additional candidates should the Court determine a neutral interpreter is necessary. For example, it appears that Sarepta has at least another interpreter available for the week at trial but has declined to disclose that interpreter's identity and qualifications.

biopharmaceutical patents) and has no prior working relationship with any party in this case. If NS is concerned about Ms. Pappas's ability to translate select technical terms, Sarepta proposes that the parties spend a few shared hours with Ms. Pappas to discuss the appropriate translation of technical terms that may be used at trial. Alternatively, Sarepta is open to NS identifying an alternative interpreter, provided that he or she has no prior working relationship with any party in this case; NS has been on notice of this issue since May, and is a Japanese biopharmaceutical company; it could surely find a neutral Japanese interpreter with pharma experience who has not been part of its litigation team. Irrespective of whether Ms. Pappas or another interpreter is selected, the interpreter should not be able to work with NS and its witnesses *ex parte*, just as *ex parte* communications with the court reporter and the Court are not permitted.

NS's proposal, designating Ms. Yumi Schweizer as a "neutral" interpreter, is inappropriate and prejudicial to Sarepta. Ms. Schweizer worked with NS's counsel and their Japanese witnesses in preparing for and defending at least four depositions, and is working with NS's witnesses and counsel in preparation for trial. NS has likely paid Ms. Schweizer tens of thousands of dollars at this point, maybe more. Even with the best of intents, this relationship raises potential bias concerns, and is prejudicial insofar as Ms. Schweizer has practiced with NS's counsel and witnesses. *See Adv. Tech. Incubator, Inc. v. Sharp Corp.*, 701 F. Supp. 2d 861, 862-63 (E.D. Tex. Apr. 5, 2010) (disqualifying defendant's interpreter at trial for the appearance of impropriety arising from translating privileged conversations preparing defendant's witnesses for deposition). This practice will benefit NS with smooth, choreographed direct examinations but will result in slow and awkward cross-examinations by Sarepta. NS's proposal in the Proposed Amended Pre-trial Order (D.I. 646), i.e., a lead interpreter and a check interpreter, will disrupt a very compressed trial, as shown in the deposition excerpts and videos submitted by each side via e-mail to the Court on the evening of December 9. Further, the deposition excerpts and videos submitted by each side demonstrate an additional problem with Ms. Schweitzer: she was often obstructionist as the check interpreter. Sarepta is concerned this behavior will repeat itself during Sarepta's cross-examination of NS's Japanese-speaking witnesses, further disrupting trial and prejudicing Sarepta. NS's proposal this morning to use Ms. Yaejoong Watkins as an alternative interpreter suffers from the same problems as affect Ms. Schweizer. Ms. Watkins has been working with NS for months and has been assisting counsel in their trial preparation.

NS's unsupported suggestion that Sarepta seeks to interrupt its direct examination is without basis. NS's request for individuals allowed to bring computers to the courtroom included *four* different interpreters. It is free to continue practicing its direct examinations with these interpreters. When the witnesses testify, both parties will be inconvenienced by the burden of translation. Indeed, the spontaneous nature of cross-examination means it will be Sarepta who bears the brunt of that inconvenience. Sarepta seeks nothing but a level playing field with translation by a sworn, neutral interpreter, not a long-time member of NS's trial team.

At 10 am Eastern this morning, NS proposed to use Mr. Paul Hersey as a "neutral" interpreter for trial. This proposal could be acceptable to Sarepta *only if* Mr. Hersey is not permitted to participate in NS's *ex parte* witness preparation sessions. If he is permitted to do so, Sarepta

will still be prejudiced as explained above, given the spontaneous nature of cross-examination. Sarepta would not object to each side's trial attorneys (not witnesses) having an hour or two separately with Mr. Hersey this week to meet and discuss preparation for trial.

## **II. Sarepta's Ability to Seek to Recover Lost Profits for the Period of April 1, 2021 to May 11, 2022**

**NS's Position:** In Delaware the interpretation of the language of a contract is a question of law.<sup>4</sup> *E.g., Prime Victor Int'l Ltd. v. Simulacra Corp.*, 682 F. Supp. 3d 428, 437–38 (D. Del. 2023). “Delaware law adheres to the objective theory of contracts, i.e., a contract’s construction should be that which would be understood by an objective, reasonable third party.” *Id.* “[T]he Court must first determine whether a contract is unambiguous as a matter of law. If the language of the contract is unambiguous, the Court interprets the contract based on the plain meaning of the language contained on the face of the document.” *JFE Steel Corp. v. ICI Americas, Inc.*, 797 F. Supp. 2d 452, 469 (D. Del. 2011) (internal citations omitted).

NS maintains that Sarepta’s internal licensing agreements at D.I. 568-10, D.I. 568-11, and D.I. 572-1 through 572-3 are unambiguous, and this Court should interpret them as demonstrating that Plaintiff Sarepta Therapeutics, Inc. was not the exclusive licensee of the ’851 Patent from April 1, 2021 to May 11, 2022 (the “relevant period”). *See* D.I. 568 (NS’ Letter Brief explaining why the contracts unambiguously prove that Sarepta was not the exclusive licensee during the relevant period). Therefore, should NS fail to prove invalidity of claim 1 of the ’851 patent at trial, Sarepta cannot recover lost profits for any NS infringement during the relevant period and *at most* can seek a reasonable royalty. *See id.* at 2-4 (explaining that no damages may be available during the relevant period).

If the Court disagrees and finds the licensing agreements create ambiguity as to Sarepta Therapeutics, Inc.’s status as an exclusive licensee, then the Court “must look beyond the language of the contract to ascertain the parties’ intentions.” *Prime Victor*, 682 F. Supp. 3d at 438. However, the Court should not consider Sarepta’s “gap filling” parole evidence because it was produced well after the close of fact discovery and on the eve of the originally scheduled trial. *See* D.I. 568 at 4-5 (explaining why exclusion of the gap filling parole evidence Sarepta produced on May 6, 2024 is the most appropriate remedy under the Third Circuit’s *Pennypack* five-factor test).

Sarepta argues that NS was not unfairly prejudiced by the late production of the gap filling evidence because NS could have sought additional discovery after the Court postponed the May 2024 trial. But by then NS had already filed D.I. 568 seeking to exclude the evidence, and the Court’s scheduling order did not provide for the reopening of fact discovery. *See*

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<sup>4</sup> The contracts do not have choice of law provisions. NS cites to Delaware and Third Circuit law herein, but to the extent the Court finds that New York law applies, both states’ laws are consistent on these issues.

D.I. 597.<sup>5</sup> Sarepta also suggests NS could have moved for summary judgment in October per the Court's scheduling order, but the Court ordered that any supplemental summary judgment motions be limited to "an issue affected by the supplemental [technical] expert reports." D.I. 597 at 2 n.1. Sarepta did not serve its new supplemental economic expert reports until more than a month after this deadline.

If the Court considers this untimely gap filling parole evidence, then at most the evidence creates a factual dispute as to whether Sarepta Therapeutics, Inc. had exclusive rights during the relevant period. *See, e.g.*, D.I. 572 at 2-3 and below herein (Sarepta arguing that the parties' performance under the agreement "is strong evidence of the existence of an agreement" or "an implied exclusive license would have existed as of 2021"; both issues of fact). The Court cannot decide this factual dispute post-trial, as Sarepta suggests; where "a contract is ambiguous," it "presents a question of interpretation for a jury." *Am. Eagle Outfitters v. Lyle & Scott Ltd.*, 584 F.3d 575, 587 (3d Cir. 2009).

Finally, contrary to Sarepta's suggestion, while NS agreed that the fact "Sarepta has exclusively licensed the Wilton Patent from UWA" is uncontested in D.I. 646-3 at ¶22, NS did not agree as to the time period.

NS respectfully requests that this Court either interpret the licensing agreements as unambiguously creating a gap in Sarepta Therapeutics, Inc.'s exclusive rights to enforce the '851 Patent or allow the jury to decide—after hearing all admitted evidence—whether Sarepta can prove a right to lost profits during the relevant period.<sup>6</sup>

**Sarepta's Position:** Sarepta is entitled to lost profits for the entirety of the damages period in this case (including from April 1, 2021, to May 11, 2022) because it has continuously held exclusive rights under the '851 Patent. Indeed, the parties have stipulated in this matter to the undisputed fact that "Sarepta has exclusively licensed the Wilton Patent from UWA." (D.I. 646-3 at ¶22). Even if Sarepta's entitlement were to be evaluated, this late-raised "dispute" is a question of law for the Court that can be adjudicated (if necessary) during post-trial briefing. Contrary to NS's equivocations, the terms of Sarepta's internal licenses as well as those of the Termination Agreement (D.I. 568-10) are unambiguous both in their effect and in the intent of the parties. Indeed, NS has not pointed to a single purported ambiguity in any agreement, only legal questions raised by the plain language of those

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<sup>5</sup> Sarepta further argues that NS could have requested the reopening of fact discovery, but NS was awaiting a ruling on its pending letter brief, in which NS made clear the evidentiary and legal issues. It was and remains Sarepta's burden to prove entitlement to lost profits, including its status as the exclusive licensee. As NS noted in its letter brief, Sarepta could have joined another party to collect reasonable royalties during the carve out period but elected not to. Sarepta could have provided disclosure of evidence in support of its lost profit theory and did not do so. Both actions were within Sarepta's control, and Sarepta did neither.

<sup>6</sup> In making this argument, NS does not concede that Sarepta will be able to introduce the gap filling parole evidence.

agreements. *See* Pretrial Conf. Tr. at 60:5-6 (“So there’s no dispute of fact if you just look at the words of the agreement.”). There is nothing for the jury to decide.

NS’s surprising and untimely insistence at the Pretrial Conference that it wants the Court to grant it *de facto* summary judgment of no lost profits for 13 months of infringing sales seven days before trial should be rejected. As a procedural matter, NS’s request comes far too late. All relevant documents were exchanged and the parties briefed these issues to the Court in May 2024. *Seven months* have passed since then. Of particular note, NS jointly negotiated and filed the proposal that became the Amended Scheduling Order (D.I. 579). That schedule included a provision for moving the Court for leave to file summary judgment motions by October 2, 2024 (*id.* at 2).<sup>7</sup> That date has come and gone. Moreover, that schedule did not include—and NS did not even propose to include—any additional discovery. Nor did NS seek any additional discovery by any other mechanism over the last seven months. Instead, NS made the tactical decision to rest on the papers that were filed in May 2024,<sup>8</sup> and should not be heard now to complain that it did not receive the discovery it did not pursue. *See, e.g., IPA Techs. Inc. v. Microsoft Corp.*, C.A. No. 18-01-RGA, 2024 WL 1797394, at \*9 (D. Del. Apr. 25, 2024) (“Plaintiff does not face prejudice as it failed to raise this issue at an earlier time when corrective action could have been taken.”); *Bayer HealthCare LLC v. Baxalta Inc.*, C.A. No. 16-1122-RGA, 2019 WL 297039, at \*2 (D. Del. Jan. 22, 2019) (no substantial prejudice when movant’s expert was able to consider late-produced documents and movant had the opportunity to conduct relevant fact discovery, but refused). NS’s argument that Sarepta was somehow responsible for re-opening discovery because Sarepta bears the burden of proving its damages borders on the absurd. In any event, Sarepta provided the full extent of discovery needed to carry its burden on lost profits: Sarepta produced dozens of documents and a sworn declaration. NS sought nothing further. Any purported prejudice NS claims is thus of its own making. In contrast, there is very real prejudice to Sarepta, *now*, on the eve of trial, as NS attempts to disrupt Sarepta’s witness preparation and presentation.

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<sup>7</sup> NS puts “[technical]” in brackets in its recounting of the Court’s Amended Scheduling Order because that word does not appear in the Court’s Order (D.I. 597 at 2). Regardless, what the Order’s plain language *does* say is that NS’s position was that “any supplemental summary judgment motions” would be due by October 2, 2024. (*Id.*) The Court agreed that the parties could seek leave to file summary judgment motions by that date. By July 2, 2024, when the Court issued the Order, NS had had possession of all relevant Sarepta internal licensing documents and supporting evidence for nearly two months. By October 2, 2024, three additional months had passed. Nothing barred NS from seeking leave from the Court to file a summary judgment motion. Instead, they waited until the Final Pretrial Conference on December 6, 2024 to make the ask. Pretrial Conf. Tr. at 59:16-21 (“So the primary ask here is if you would agree with us on that, then you would just hold that they can’t tell the jury for a one-year period they can’t [*sic*] get lost profits.”).

<sup>8</sup> When directly asked by the Court at the Final Pretrial Conference, “[W]hy didn’t you follow up at that point in time?”, NS’s counsel responded, “It was because we had already filed for our relief.” Pretrial Conf. Tr. at 64:10-15.



NS's request should also be rejected based on the substance of the parties' positions (as addressed in Sarepta's May 8, 2024 letter brief (D.I. 572)). NS's argument that Sarepta's lost profits period was disrupted centers on an incorrect and self-serving interpretation of a set of three agreements between Sarepta and its wholly-owned subsidiary ST International Holdings Two, Inc. ("Holdings"): (1) a U.S. Sublicense Agreement (D.I. 568-11), which undisputedly grants Sarepta sufficient exclusive rights to claim its lost profits; (2) an Ex-U.S. Sublicense Agreement (D.I. 572-1); and (3) a Termination Agreement (D.I. 568-10) that terminated an earlier manufacturing agreement between Sarepta and Holdings (D.I. 568-8), under which, also undisputedly, Sarepta had the exclusive right to manufacture and commercialize patented products.

These documents reflect that all three agreements were drafted together, act as a unified understanding, and are expressly made effective on the same date, April 1, 2021 (D.I. 572-4 ¶ 5). Despite this evidence, NS argues that the U.S. Sublicense Agreement did not become effective until its date of signature, May 11, 2022, but the Termination Agreement became effective on April 1, 2021 (despite being signed in January 2022) and therefore, there is a gap in Sarepta's exclusive rights. This argument fails for several reasons.

**First**, NS's argument contradicts the express intent of the parties to the U.S. Sublicense. All three of these agreements expressly state that their effective date is April 1, 2021, and Sarepta and Holdings intended them all to be effective as of the same date. Adopting NS's interpretation of the U.S. Sublicense requires ignoring not only the express terms of the agreements, but the intent of the parties and thus, violates applicable contract law. *See Greenfield v. Philles Records, Inc.*, 98 N.Y.2d 562, 569 (2002) ("The fundamental, neutral precept of contract interpretation is that agreements are construed in accord with the parties' intent [and] [t]he best evidence of what parties to a written agreement intend is what they say in their writing" (citations and internal quotation marks omitted)).

**Second**, the Termination Agreement expressly states that it is only terminating the earlier agreement because the U.S. Sublicense made it unnecessary. Specifically, the Termination Agreement states in the recitals that because Holdings "has now sublicensed" the relevant patents, Holdings "will no longer require Sarepta's services to manufacture or distribute products under [the Manufacturing Agreement]." (D.I. 568-10 at 1). This language makes clear that Sarepta and Holdings only intended the Termination Agreement to come into effect *because* the U.S. Sublicense had negated the need for the Manufacturing Agreement. Having them come into effect on different dates as NS argues would be non-sensical.

**Third**, the parties to the agreements acted at all times (beginning on April 1, 2021) as if the agreements were in effect. Sarepta never ceased acting as the exclusive licensee of the patents and the sole and exclusive manufacturer and seller of patented products. Moreover, Sarepta paid royalties to Holdings under the terms of the U.S. Sublicense beginning in Q2 2021 through to today. (D.I. 572-4 ¶¶ 20-21). Performance is strong evidence of the existence of an agreement. *See In re Abbale*, 475 B.R. 334, 339 (Br. E.D.N.Y. 2012). NS attempts to dismiss this evidence—which it itself demanded, *see* D.I. 568-12—as "self-serving gap filling evidence" and wants to exclude it. As the Court recognized at the Pretrial Conference, NS not wanting to know the answer to a question it asked is not grounds for

exclusion of evidence. Pretrial Conf. Tr. at 64:5-7 (“I’m not going to rule that NS can rely on the documents it got on May 3rd but not the ones – or that the other side can’t [rely] on the ones it got on May 6th.”).

**Fourth**, the fact that the agreements were not all signed on the same date is irrelevant. New York law (which governs the agreements) does not require a formal signature for an agreement to be effective. *See Flores v. Lower East Side*, 4 N.Y.3d 363, 368 (2005). Moreover, NS’s argument is internally inconsistent in that it asserts the Termination Agreement became effective as of its stated effective date of April 1, 2021, despite being signed in January 2022, but the U.S. Sublicense only became effective when signed in May 2022.

Finally, at a minimum, there is evidence of an implied exclusive license between Sarepta and Holdings for the challenged period given that Sarepta acted as the sole manufacturer and seller of the patented products and paid royalties to Holdings. *See, e.g., Aspex Eyewear, Inc. v. Altair Eyewear, Inc.*, 288 F. App’x 697, 705 (Fed. Cir. 2008); *Viam Mfg., Inc. v. Iowa Export-Import Trading Co.*, 243 F.3d 558 (table), 2000 WL 1234623, at \*2-\*3 (Fed. Cir. 2000).

For these reasons, Sarepta should be permitted to claim its lost profits for the entirety of the damages period. In the alternative, this should be an issue for post-trial briefing. The parties’ presentations to the jury should not be impacted by this late-raised question of law.

### **III. Number of NS Patent Claims to Be Tried**

**NS’s Position:** NS intends to proceed to trial on three claims: claim 1 of the ’092 Patent, claim 2 of the ’461 Patent, and claim 4 of the ’217 Patent.

Each claim has different claim language, and the claims substantively differ in terms of the nucleobases they permit (the ’092 Patent allows “cytosine, thymine, adenine, and guanine,” whereas the ’461 and ’217 Patents additionally allow for “uracil”). NS foresees multiple ways in which these substantive differences may matter at trial. First, Sarepta continues to challenge “nexus” for objective indicia of non-obviousness (notwithstanding that each claim narrowly covers VYONDYS 53), and the nucleobases are potentially relevant for nexus because VYONDYS 53 has thymine bases. Second, despite dropping its written description challenge, NS expects that Sarepta will narratively critique the NS Patents for not providing testing data for the exact same antisense molecule found in VYONDYS 53, and the nucleobases are relevant to the testing data because the NS Patents report high levels of exon 53 skipping for SEQ ID. 57—an ASO that targets the exact same site (“H53\_36-60”), but used uracil bases (GUUGCCUCCGGUUCUGAAGGUGUUC). Third, NS expects Sarepta to focus on the timeline, and each patent has a different issuance date. The ’092 Patent and ’461 Patent issued before Sarepta’s December 2019 launch of VYONDYS 53, but the ’217 Patent issued roughly 6 months afterwards.

Provided that Sarepta agrees (1) that nexus exists between each of these claims and evidence relating to its infringing VYONDYS 53 product; and (2) that it will not argue or otherwise



suggest that the NS Patents fail to disclose their claimed invention (including the active ingredient for VYONDYS 53), NS would agree that the '092 Patent, claim 1 is representative of all three claims and that the verdict form can be consolidated accordingly. NS would also agree not to argue that the number of issued patents should serve as a proxy for how thorough the Patent Office's prosecution of the asserted patents was (*i.e.*, the specific concern Sarepta's counsel raised at the Pretrial Conference).

**Sarepta's Position:** Nippon Shinyaku should be ordered to limit its trial presentation to one asserted patent. Both sides agree that the asserted claims rise and fall together, and that Nippon Shinyaku's claimed damages are independent of the number of asserted patents or claims. As demonstrated at the Pretrial Conference, Nippon Shinyaku cannot show any meaningful differences between the asserted claims. While NS has strained to identify minimal wording differences they are distinctions without differences, since both sides' experts treated the patents interchangeably for purposes of both validity and damages. What's more, NS is now making up phantom issues, raising "nexus" where, in last night's meet and confer, Nippon Shinyaku's counsel acknowledged that none of its experts opined on nexus, and nobody has ever asserted that any nexus argument would be any different among the different patents. Nippon Shinyaku also failed to identify evidence of their experts relying on the distinctions articulated above. Sarepta reiterates that it does not intend to re-raise its written description claim against the NS patents

Both sides agreed, in open court Monday, that the patents rise or fall together. While NS says it will not "argue" that the number of patents shows that they must be valid, the jury may nevertheless weigh NS's number of patents (versus Sarepta's) into the equation, which is the only reason NS could possibly be fighting this issue so hard, after acknowledging that it does not impact the substantive issues in the case. The Court should limit Nippon Shinyaku's trial presentation to one asserted patent to focus the issues for the jury, avoid confusion, avoid wasting time and resources, and, importantly, avoid the possibility of an inconsistent verdict, which could necessitate an entirely new trial (NS has no response to this point). To the extent Nippon Shinyaku is not prepared to drop the other patents completely, Sarepta proposes that the parties stipulate that the jury verdict will be applicable to the remaining two asserted patent claims.

#### **IV. Inequitable Conduct Bench Trial Sequencing Proposal**

**NS's Position:** NS proposes that: 1) opening statements and USPTO practice and procedure experts Dr. Kamholz and Mr. Hirshfeld should go forward on Tuesday after the jury is dismissed; 2) the technical experts Dr. Hastings and Dr. Dowdy testify on Friday during jury deliberations; and 3) the parties submit the deposition designations for the Court to view at its convenience, with time charged to the parties according to the pre-trial order. As agreed during the pre-trial conference, Dr. Wilton may testify in the bench trial on the same day(s) as his testimony during the jury trial.

Sarepta's proposal is unworkable. Forcing Dr. Hastings to testify in the evening immediately after she testifies regarding UWA patent invalidity in the jury trial would prejudice NS's ability to prepare with her for her rebuttal testimony concerning the validity of the NS

patents. Sarepta would suffer no such prejudice with Dr. Dowdy because he will not have rebuttal testimony before the jury. Further, there is no reason that Mr. Hirshfeld must wait until after Dr. Hastings testifies in the bench trial to testify before the Court. Mr. Hirshfeld is a legal expert, not a technical expert. He will be responding to his counterpart Dr. Kamholz, not Dr. Hastings. And, in any event, testimony is frequently taken out of order in bench trials to accommodate scheduling. Sarepta's concern about not having enough time on Friday afternoon is best ameliorated by having Mr. Hirshfeld testify on Tuesday, after Dr. Kamholz.

**Sarepta's Position:** Sarepta proposes that both parties present their opening statements for the bench trial on Monday evening, after the jury is excused. Then, for any witnesses testifying at both the jury and bench trials, we propose that they present their bench trial testimony at the first possible opportunity (e.g., that same evening or, if necessary, while the jury is deliberating) after they complete their jury testimony on the subject of the Wilton patent. Sarepta believes that the parties should move the bench trial forward as far as possible as quickly as possible, as it is unknown how long the jury will deliberate and whether they will have any questions. If there are questions or if the jury returns quickly, it could take up the time on Friday afternoon that NS proposes be set aside for Dr. Hastings' and Dr. Dowdy's testimony. Sarepta does not object to NS presenting testimony from Dr. Kamholz before the testimony of other witnesses upon which his testimony relies, but believes that Mr. Hirshfeld's rebuttal testimony should come after NS completes its case-in-chief.

Sarepta also proposes that the parties submit deposition testimony to the Court in writing or video for the Court to read or review at its convenience, and that the time be charged against the offering party as if it were played in court. Should the Court prefer to play the deposition testimony during the bench trial, Sarepta proposes that such testimony be played Monday evening, after opening statements.

NS's complaints about needing time to prepare Dr. Hastings are a problem of its own making. In April 2024, NS argued that the Court should try its inequitable conduct claim at the same time as the jury trial, while Sarepta's position was that the inequitable conduct issues "should be decided by the Court at a later time." D.I. 526 at 2; *see also* April 18, 2024 Hearing Tr. 17:1-11 (NS's counsel arguing "Again, you know, to the extent that Sarepta's counsel is suggesting that we should just set the inequitable conduct issues aside for later, we don't think that makes any sense at all."). At that hearing, the Court sided with NS and explained that the inequitable conduct issues would be tried in "a separate bench trial to occur in the evenings after the jury is released." April 18, 2024 Hearing Tr. 18:15-21. NS should not be permitted to force Sarepta to rebut an inequitable conduct case that NS has yet to submit by dictating when Sarepta must present its rebuttal witnesses. In April, NS got what it asked for—that its inequitable conduct claim be tried at the same time as the jury issues. That NS now feels like it cannot prepare its expert witness according to the schedule NS asked for is not a reason to prejudice Sarepta by dictating the order in which its witnesses must testify.

**V. Potential Recovery of Lost Profits if Both Side's Patents Are Found to Be Valid**

**Joint Statement:** As indicated at the Pretrial Conference, the parties agree that this issue can be dealt with after trial, if necessary, provided that the verdict form asks the jury to provide both their lost profits assessment and a royalty rate. The parties will continue to work on agreeing on a joint proposed verdict form, and do not waive their rights to object in the event they cannot reach such agreement. After trial, if (and only if) (1) both parties' patents are found valid, and (2) one or both sides are awarded lost profits, the parties can brief the entitlement to lost profits issue (including whether the issue was forfeited). And, should the Court hold that lost profits would be inappropriate in that circumstance, the royalty numbers could be applied.

Given the Court's interest in this point at the Pretrial Conference, the parties have provided their initial positions on the legal issue of the appropriateness of lost profits in this scenario below. Both parties agree that further briefing on this issue can be done after trial, if necessary.

**NS's Position:** On December 8, 2024 at 8:45pm the night before the pretrial conference, Sarepta raised new damages theories: (1) that if both parties' patents are found valid, then lost profits are not available, and (2) that even if lost profits are available, the parties' experts did not correctly perform the lost profits calculation.

As a preliminary matter, Sarepta's new theories are untimely and have been forfeited. NS sought Sarepta's detailed damages contentions during fact discovery, which closed over a year ago. Sarepta failed to raise either of its contentions in any of its responses to contention interrogatories. Sarepta also failed to raise these contentions in any of the seven expert damages reports from its expert Mr. John Jarosz, dated (1) September 8, 2023, (2) October 11, 2023, (3) October 27, 2023, (4) April 12, 2024, (5) April 19, 2024, (6) November 5, 2024, and (7) November 12, 2024. Mr. Jarosz also did not raise these issues at his deposition, instead maintaining that lost profits are available. Nor did Sarepta's counsel raise these theories before the submission of the pretrial order on November 26, 2024. Sarepta has raised its damages theories too late, and the Court need not consider them.

Sarepta's request also fails on the merits, as Sarepta's legal theory that lost profits are not available if both parties' patents are found valid is incorrect. Contrary to Sarepta's suggestion herein, there is no "zeroing out" of lost profits "as a matter of straightforward economics." Sarepta's contention is seemingly premised on the idea of "blocking patents," that NS is not entitled to lost profits because it could not have made additional sales of VILTEPSO due to the existence of Sarepta's patent (and vice versa). But this does not reflect the facts of this case. Sarepta assumes that Sarepta would have used its patent to obtain an injunction to prevent NS from selling VILTEPSO, but neither side has ever sought an injunction to keep VILTEPSO or VYONDYS 53 off the market. Nor could they, given the very strong public interest in allowing these critical medications to remain available. The idea of a "blocking patent" simply does not apply to this case. Accordingly, even if both parties' patents are valid, lost profits are still available for both parties.

Moreover, the case law makes clear that lost profits are an appropriate measure of damages based on a purely hypothetical situation:

In *Aro Manufacturing*, the Supreme Court stated that the statutory measure of “damages” is “the difference between [the patent owner’s] pecuniary condition after the infringement, and what his condition would have been if the infringement had not occurred.” . . . The “but for” inquiry therefore requires a reconstruction of the market, as it would have developed absent the infringing product, to determine what the patentee “would . . . have made.” . . . Reconstructing the market, ***by definition a hypothetical enterprise***, requires the patentee to ***project economic results that did not occur***. To prevent the hypothetical from lapsing into pure speculation, this court requires sound economic proof of the ***nature of the market and likely outcomes with infringement factored out of the economic picture***. . . . Within this framework, trial courts, with this court’s approval, consistently permit patentees to present market reconstruction theories showing all of the ways in which they would have been better off in the “but for world,” and accordingly to recover lost profits in a wide variety of forms.

*Grain Processing Corp. v. Am. Maize-Products Co.*, 185 F.3d 1341, 1350 (Fed. Cir. 1999) (emphasis added) (internal citations omitted). The lost profits framework therefore permits the jury to consider two separate hypothetical scenarios to determine damages, with each claim separately evaluated.

Sarepta’s cited case law is irrelevant to the issue at hand. Sarepta relies on *Mentor Graphics Corp. v. EVE-USA, Inc.*, 851 F.3d 1275, 1285 (Fed. Cir. 2017), and *Parker-Hannifin Corp. v. Champion Lab ’ys, Inc.*, 2008 WL 3166318, at \*6 (N.D. Ohio Aug. 4, 2008). Both of those cases address the first two *Panduit* factors that are used to establish lost profits: (1) demand for the patented product and (2) absence of acceptable non-infringing substitutes. Under the *Panduit* factors, the patentee may be entitled to lost profits by showing that (1) there was a demand for the patented features of the product, and (2) besides the patentee’s own product, there were no other substitutes on the market that did not also infringe the patent that is subject to the lost profits claim. In other words, the “proprietary rights” discussed in both of these cases is the patent that is the subject of the lost profits claim—not an alleged infringer’s separate or competing patent. An alleged infringer’s separate patent rights simply play no role in the lost profits analysis. Instead, the lost profits analysis requires the Court to look at whether other alternative third-party products infringe the patentee’s patent, not at whether the patentee’s product infringes other third-party patents.

Sarepta’s second theory, that the parties’ experts did not correctly perform the lost profits calculation, is a factual dispute that can be explored on cross-examination. As the caselaw states, parties can present alternative “market reconstruction theories . . . to recover lost profits in a wide variety of forms.” *Id.* The experts have made those market reconstructions based on their opinions and expertise and should be permitted to present them to the jury consistent with the opinions set forth in their respective reports.

Further, Sarepta's second theory is flawed. Sarepta's argument is that, under the lost profits analysis, if both parties' patents are valid, each party would have additional costs that were not appropriately calculated. For example, for the NS lost profits analysis:

- The experts correctly assumed that VYONDYS 53 would never have been launched;
- The experts calculated the number of additional sales of VILTEPSO that would have been made in this but-for world;
- The experts calculated some costs that NS would have incurred due to these additional sales;
- The experts ***did not*** calculate additional patent royalty costs:
  - Because Sarepta had a patent covering VILTEPSO, NS should have paid a royalty to Sarepta for these additional sales; and
  - This royalty would have been an additional cost that should have been subtracted from the lost profit analysis.

NS does not agree that this additional calculation is necessary. However, should the Court believe that it is legally required, it is a simple calculation that the experts can perform based on information that each party's expert has already disclosed in their opinions.

Finally, NS' proposed verdict form already asks the jury to provide a reasonable royalty rate even if it awards lost profits, which is consistent with Sarepta's proposal below.

**Sarepta's Position:** This is an unusual case, in which competing claims of patent infringement by both sides are being tried in front of the same jury in the same case. In addition, both party's products have been held to infringe the other party's patents. *See* D.I. 541; D.I. 544. If both sides' patents are held not invalid at trial, in the but-for infringement world, neither party could lawfully manufacture its product to exploit demand as required under *Panduit*. In other words, neither party would have the legal capacity to make the other party's sales, because each such sale would be an unlawful infringing act of the other party's patents. Thus, the parties' competing lost profits claims would be premised on a finding that both parties could have made additional sales (to satisfy the *Panduit* standard), but in fact neither party would be permitted to make the additional sales because they would be infringing the other side's patent. This makes no logical sense.

While Sarepta is unaware of any ruling by the Federal Circuit on the issue of whether, in a case where each party asserts a lost profits damages claim against the other, lost profits are available based on sales of each side's infringing products, courts have looked at whether products are infringing in making lost profits determinations. For example, in *Mentor Graphics Corp. v. EVE-USA, Inc.*, the Federal Circuit affirmed a lost profits damages award where the patentee (Mentor) "had proprietary rights to the only means of satisfying th[e] demand" for the sales subject to the lost profits claim, such that "for these particular sales, no other party could satisfy the *Panduit* factors, making it impossible for multiple patentees to obtain lost profit damages for the same sales." 851 F.3d 1275, 1285 (Fed. Cir. 2017); *see also Parker-Hannifin Corp. v. Champion Lab'ys, Inc.*, 2008 WL 3166318, at \*6 (N.D. Ohio Aug. 4, 2008) ("if the [defendant's] alleged substitutes infringe any of the plaintiffs' patents, those substitutes are illegally on the market and it would thus be reasonable to conclude that



plaintiffs would make those sales instead”).<sup>9</sup> By extension, if both Sarepta/UWA and Nippon Shinyaku hold proprietary rights that block each other’s sales, it would be impossible for either side to make sales to which lost profits damages would apply. Contrary to NS’s claim above, blocking proprietary rights are not limited to just the patentee’s patent, but extend to any third-party patents that would be infringed by the product proposed to be sold. *See, e.g., AstraZeneca AB v. Apotex Corp.*, 985 F. Supp. 2d 452, 481 (S.D.N.Y. 2013) (identifying third party patents as blocking a party’s ability to make hypothetical sales).

Moreover, neither side has accounted in their lost profits damages assessments for the additional damages they would owe the other side in the “but-for” world where they sold more infringing products. In other words, if NS had sold 100 more units of product in the but-for world, it would also owe damages to Sarepta for that infringement, likely zeroing out any lost profits as a matter of straightforward economics.

That said, Sarepta agrees with NS that the issue can be dealt with after trial, if necessary, rather than needing to revise the jury instructions or the verdict form. As long as the jury is asked to provide both their lost profits assessment and a royalty rate, the parties can brief the entitlement to lost profits if (and only if) (1) both parties’ patents are found valid, and (2) one or both sides are awarded lost profits. And if the Court agrees that lost profits would be inappropriate in that circumstance, the royalty numbers can be applied.

## **VI. Mr. Hosfield’s Damages Scenarios**

**NS’s Position:** NS’s damages expert Mr. Mark Hosfield provided alternative calculations for different damages scenarios depending on different factual circumstances. For example, some of Sarepta’s infringing VYONDYS 53 units are distributed to customers free of charge, and Mr. Hosfield provided alternative damages calculations based on the percentage of those distributions that could have been NS Pharma VILTESPO sales in a but-for world. Similarly, Mr. Hosfield provided alternative calculations to allow the jury to award lost profits or reasonable royalty damages.

Sarepta now argues that it needs to know which specific alternative calculations Mr. Hosfield will present at trial to “avoid trial by ambush.” But there is no “trial by ambush” in this scenario. Mr. Hosfield has disclosed his various alternative damages calculations in his reports and will present testimony consistent with his already disclosed opinions. Sarepta’s request is simply a demand that NS share its direct examination witness outlines, which is simply not reasonable and is not being done for any of the other witnesses in this case.

At this point Mr. Hosfield intends to present both lost profits and reasonable royalty scenarios to the jury. But even that plan may change depending on various factors, including (i) how specific evidence that Mr. Hosfield relies upon for various alternatives comes into

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<sup>9</sup> The discussion in both these cases refutes NS’s incorrect assertion that this issue is not a problem on the facts here because neither party has sought an injunction. Both cases assess whether other products were blocked from being legally on the market because they infringed patents.

the record, and (ii) counsel's judgement as trial progresses, including as to the jury's ability to understand multiple alternative scenarios and time constraints. Accordingly, Sarepta's demand that NS identify the specific opinions that Mr. Hosfield intends to present is unreasonable and should be rejected. Like all experts, Mr. Hosfield will present testimony consistent with his expert reports that have already been disclosed to Sarepta in this case.

NS should not be forced to limit its damages theories before trial even begins, especially at a time that Sarepta is adding issues related to damages. *See* Section V, *supra*. Moreover, Sarepta's demand that NS disclose no more than three damages scenarios simply cannot be granted as Mr. Hosfield may present more than three scenarios. However, as a compromise, NS can limit itself to four damages scenarios (in other words, disclose which four scenarios of the eight it is no longer pursuing) by Friday, December 13, at 5 PM.

**Sarepta's Position:** NS's damages expert Mark Hosfield presented *eight* different damages scenarios related to infringement of the NS Patents in his November 5, 2024 Second Supplemental Expert Report and Disclosure. The scenarios vary in their assumptions regarding (1) the damages period for NS damages and/or (2) the percentage of free or unpaid units that Sarepta distributes as part of patient-assistance programs for which NS claims damages. Three of these scenarios were presented for the first time last month in Mr. Hosfield's November 5, 2024 report.

Less than a week before trial begins, it is untenable for Mr. Hosfield to still be maintaining eight different possible theories for NS's damages. The choice of theories to present is fully within NS's control, and is not contingent on any pending disputes still to be resolved by the Court. In a compressed, highly complicated trial such as this one, NS's delay in identifying the damages theories it will actually pursue at trial amounts to trial by ambush. And it could significantly affect cross-examination of NS's fact witnesses, who will testify before Mr. Hosfield, as well. For example, NS has not yet informed Sarepta whether it is actually going to seek lost profits for products Sarepta gave away to patients who could not afford to pay for the treatments. As far-fetched as that seems, if NS does not drop those scenarios, Sarepta will be forced to waste valuable time questioning NS's fact witnesses about how those patients would magically have \$800k per year to pay NS instead. NS knows what its damages theories will be; Sarepta should not need to prepare for 8 different scenarios. Sarepta respectfully requests that the Court order NS to inform Sarepta of no more than three (3) damages scenarios that it plans to present to the jury by no later than 5 PM ET on Friday, December 13.<sup>10</sup>

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<sup>10</sup> To clarify NS's purported "compromise" offer, NS's counsel offered to identify four scenarios that it would not present to the jury, not the scenarios that it *would* present to the jury.

Honorable Jennifer L. Hall

49006

December 11, 2024

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Respectfully submitted,

*/s/ Amy M. Dudash*

Amy M. Dudash (DE Bar No. 5741)

cc: All Counsel of Record (via CM/ECF)